UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,389	07/01/2005	Yoshifumi Yanagita	12218/67	6379

23838 7590 12/10/2007

KENYON & KENYON LLP
1500 K STREET N.W.
SUITE 700
WASHINGTON, DC 20005

EXAMINER	
LILLING, HERBERT J	
ART UNIT	PAPER NUMBER
1657	
MAIL DATE	DELIVERY MODE
12/10/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/541,389	YANAGITA ET AL.	
	Examiner	Art Unit	
	HERBERT J. LILLING	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. Receipt is acknowledged of a request for reconsideration filed November 09, 2007 for this application, which is a 371 national phase application of PCT/JP2004/000416 filled 20 January 2004, claiming priority to Japanese Application No. 2003-011099 filed 20 January 2003.

The continuing data should be inserted on page 1 of the specification.

2. Claims 1-20 remain pending in this application.

3. The arguments submitted have been found not to be persuasive to withdraw the rejections as recited:

> Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harrison et al; or Osamu et al. JP 2001/057895 [Reference 1] or Walker et al EP 0046017 or further in view of each other plus further in view of References 2, 3, 4 or 5 for specific claims.
>
> The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
>
> 1. Determining the scope and contents of the prior art.
> 2. Ascertaining the differences between the prior art and the claims at issue.
> 3. Resolving the level of ordinary skill in the pertinent art.
> 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
>
> Harrison et al teaches the same process steps Claims 1, 6, 7, 8, 9, 10, 11, 14, 15, 16 and 20 for the claimed subject matter as recited in the Abstract except for the washing of the PHA with water or hydrophilic solvent:

> Mechanical cell disruption by high pressure homogenisation or high speed bead mills is currently the general method of choice for the large scale disruption of micro-organisms; however, deleterious effects include the high energy requirement, the need for efficient cooling to prevent the excessive heating of the product and the micronisation of cell debris. Certain chemical treatments for microbial cell disruption alter the permeability of bacteria and yeasts, allowing partial release of soluble products. Such treatments are insufficient for the recovery of granular intracellular products. As cell wall strength has been cited as a major factor influencing the requirements for efficient mechanical disruption, the use of chemical pretreatment to decrease cell wall strength prior to mechanical breakage by homogenisation has been considered. The :following treatments were shown to increase the sensitivity of the
> • Gram-negative bacterium, Alcaligenes eutrophus, to disruption: alkaline pH shock, the addition of an anionic detergent, inc,'ease of the monovalent cation concentration, the addition of EDTA and enzymic lysis by lysozyme. These pretreatments allow equivalent disruption to be achieved at lower operating pressures or fewer passes through the homogeniser. Alkaline pH pretreatment at pH 10.5 allowed a 37.5% increase in soluble protein release on subsequent homogenisation. An increase of some 30% in soluble protein release was found following prior addition of 0.137 M monovalent cations (Na÷ or K÷) at 60 °C. Treatment with an anionic detergent showed a considerable decrease in the nUmber of passes required through the homogeniser. Maximum cell rupture can thus be accomplished at reduced energy-inputs.
> Abbreviations: HPH- high pressure homogenisation; PHB- poly-/3-hydroxybutyrate; SDS- sodium

Harrison et al teaches each of the steps required which includes the physical disruption which is carried out by a high pressures homogenizer for the recovery of PHB polymer as well as the pretreatment with an enzyme and or an anionic detergent [surfactant].

Osamu et al teaches the same method steps for the recovery of PHA which includes the step of adding an alkali and/or a surfactant to a suspension of microbial cells of PHA-containing microorganism, as noted to be Alcaligene eutrophus which contains a transferred PHA synthase gene from Aeromonas caviae which reference abstract does not specify that the suspension an aqueous but the Japanese patent indicates that the additives contain water as noted in para [0029]. Osamu teaches in the disclosure on pages 2-3 various copolymers of 3-HB and 3HV.

Osamu clearly indicates the use of a surfactant within the scope of claim 11.

The abstract of the Osamu et al reference does not indicate that there is a physical disruption treatment to obtain the PHA from the cell.

Walker et al teaches in Example 1, the process of recovering PBH by adding an alkali to an aqueous suspension of Alcaligenes eutrophus which flocculants were separated by decanting from the aqueous suspension.

The reference decanting step is considered to be a physical separation.

Claims 2, 7 and 8-9

Walker teaches on page 3 that the cells are contacted with a solvent to solubilize the lipids and cells prior to the PHB-extraction.

Walker also teaches that the addition of alkali is added to increase the pH in the range of 8-12 on page 2, pH 8.5-12 on page 3 and pH 9 in Example 1, which is within the scope of the claimed subject matter.

Walker teaches the use of methanol and acetone for washing as taught in Example 1 for Claims 12-13

Masako, Reference 2 or Reference 3, each one teaches the advantages of adding an alkali to an aqueous suspension of PHA containing microorganisms by controlling the temperature and concentration to obtain granular particles of the PHA.

Walker does not indicate any specific alkali.

Masako, Reference 3, teaches in column 3 line 29, LiOH, KOH and NaOH.

Claims 3-5

Osamu et al teaches copolymers which includes the 3 HH, 3HB and 3HV.

Claims 6 and 20

Harrison et al clearly teaches the same process for employing a high pressure homogenizer as indicated above.

Honma et al, U.S. 6,808,907 teaches commonly used processes for separating the cells from the PHA products as recited:

> The method for producing polyhydroxyalkanoate according to claim 13, wherein said step of obtaining the crushed product by crushing cells is performed by at least one selected from the group consisting of ultrasonication method, homogenizer method, high-pressure crushing method, bead impact method, milling method, grinding method, and freeze-thawing method.

Claim 10

Reference 4 [WO/22659] teaches the addition of an enzyme that aids in the separation and purification of PHA products by dissolving the cell walls, which aids in the recovery of the PHA, which includes the claimed lipid degrading enzymes or/and cell wall degrading enzymes.

Claims 14-20

Walker et al teaches the microorganisms as well as Osamu for the PHA containing microorganism.

Thus, the above references are considered to render the instant claims prima facie obvious in view of the teachings of the references either Osamu or/and Walker further in view of the additional references as noted by 2, 3, 4 and 5 absent unexpected or unobvious results or process steps.

Thus, claim 1 which recites the following:

> " A method for recovering a polyhydroxyalkanoate from a polyhydroxyalkanoate-containing microbial cell which comprises the following steps (a) and (b); (a) a step comprising adding an alkali to an aqueous suspension of the polyhydroxyalkanoate-containing microbial cell while stirring and carrying out a physical disruption treatment to disrupt the cell, solubilizing or emulsifying cell substances other than the polyhydroxyalkanoate in said cell, and then separating the polyhydroxyalkanoate from the aqueous suspension, and (b) a step comprising treating the separated polyhydroxyalkanoate with an enzyme and/or a surfactant to solubilize impurities adhering to the polyhydroxyalkanoate or to solubilize them after decomposing, and then washing the polyhydroxyalkanoate with a hydrophilic solvent and/or water.";

Which claimed subject matter is considered to be prima facie obvious in view of the disclosure of the prior art.

Each of the claimed subject matter is clearly anticipated especially in view of step (a) based on Harrison et al, Walker et al or Honma et al for the alkali treating step which includes the physical disruption of the cell.

The step of washing is clearly taught in several of the other references to purify the PHA as taught by Walker et al.

It is acknowledged that not one of the above references anticipates the claimed subject matter for the broad claim 1, however, there is considered absolutely no patentable subject matter that is not obvious over the references of record that demonstrates unexpected or unobvious process steps which includes the alleged unexpected unclaimed process step in the specification which states:

> "a treatment at such a low temperature as 20 to 40.degree. C. becomes possible, and the molecular weight decrease might be suppressed to 10% or less even in the case of PHBH. Namely, it is particularly preferred to carry out the physical disruption in a pH level of 9 to 13.5, at 20 to 40.degree. C. When the microbial cells are disrupted under such

> preferable alkali condition, more reproducible result may be obtained." ;
>
> which low temperature disruption by a high pressure homogenizer is clearly taught by the prior art as noted above for the same reasons of lower temperature to obtain a greater disruption of the PHA.

The basic argument as recited by Applicant:

> "Claim 1 is directed to a method of recovering a polyhydroxyalkanoate from a polyhydroxyalkanoate-containing microbial cell, which includes the step a) of adding an alkali to an aqueous suspension of the polyhydroxyalkanoate-containing microbial cell ***while*** stirring and carrying out a physical disruption treatment to disrupt the cell. Neither Harrison, Osamu, or Walker disclose all the limitations of claim 1.";

has been considered to be not persuasive especially in view of the new Supreme Court Decision KSR :

Further in light of the Supreme Court's recent decision in KSR International Co. v. Teleflex Inc (TFX) ., 82 USPQ2d 1385 (2007) based on the reasoning may still include the established Court of Appeals for the Federal Circuit standard that a claimed invention may be obvious if the examiner identifies a prior art teaching, suggestion, or motivation (TSM) to make it, however, the Guidelines explain that there is no requirement that patent examiners use the TSM approach in order to make a proper obviousness rejection. Furthermore, the Guidelines point out that even if the TSM approach cannot be applied to a claimed invention, that invention may still be found obvious.

If there are any differences with respect to the obvious based on the claimed subject matter pertaining to adding an alkali to an aqueous suspension ***"...while*** stirring and carrying out a physical disruption treatment.." which step would have been within the skill of the ordinary person in the pertinent art to reasonably to utilize the process step to carrying out the claimed process.

4. In view of the allowance of Miyamoto et al. application claims in Ser No 10/507414 which were allowed based on the following pending claims to be issued:

> 1. A method of producing a poly-3-hydroxyalkanoioc acid, which comprises carrying out a **physical disruption treatment of a suspension** of poly- 3-hydroxyalkanoic acid-containing microbial cells **with adding an alkali thereto** **either continuously or intermittently** and, thereafter, separating the poly-3-hydroxyalkanoic acid.
> 2. The method according to Claim 1,wherein said addition of an alkali is carried out with controlling the pH of the suspension.
> 3. The method according to Claim 2,
> wherein the pH of the suspension is controlled between 9 and 13.5.
> 4. The method according to Claim 1, wherein said physical disruption treatment is carried out under stirring of said suspension.
> 5. The method according to Claim 1,
> wherein said physical disruption treatment is carried out at the temperature not less than 20°C and below 40°C.
> 6. The method according to Claim 1,
> wherein the poly-3-hydroxylkanoic acid is a copolymer comprising of D-3-hydroxyhexanoate (3HH) and one or more other 3-hydroxyalkanoic acids.
> 7. The method according to Claim 6,
> wherein the poly-3-hydroxyalkanoic acid is a binary copolymer comprising of D-3-hydroxybutyrate (3HB) and D-3-'hydroxyhexanoate (3HH) or a ternary copolymer

Based on the instant claim one which recites:

> 1. A method for recovering a polyhydroxyalkanoate from a polyhydroxyalkanoate-containing microbial cell which comprises the following steps (a) and (b);

> **(a) a step comprising adding an alkali to an aqueous suspension of the polyhydroxyalkanoate-containing microbial cell while stirring and carrying out a physical disruption treatment to disrupt the cell,** solubilizing or emulsifying cell substances other than the polyhydroxyalkanoate in said cell, and then separating the polyhydroxyalkanoate from the aqueous suspension, and ....
> (b) a step comprising treating the separated polyhydroxyalkanoate with an enzyme and/or a surfactant to solubilize impurities adhering to the polyhydroxyalkanoate or to solubilize them after decomposing, and then washing the polyhydroxyalkanoate with a hydrophilic solvent and/or water.

Claims 1-20 are **provisionally rejected** on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims of copending Application No. 10/507,414 in view of the art of record in this application whereby step (a) is obvious in view of the copending application.

This is a provisional obviousness-type double patenting rejection.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Therefore:

Claims 1-20 are rejected under double patenting as being unpatentable over copending application 10/507,414 further in view of Harrison et al ; or Osamu et al . JP 2001/057895 [Reference 1] or Walker et al EP 0046017 or further in view of each other plus further in view of References 2, 3, 4 or 5 for specific claims.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The provisional application clearly is within the scope of step (a) of the claimed two step process and the additional references renders prima facie obvious to one of ordinary skilled in the art to solubilize and purify the PHA as claimed: ".....

....

"treating the separated polyhydroxyalkanoate with an enzyme and/or a surfactant to solubilize impurities adhering to the polyhydroxyalkanoate or to solubilize them after decomposing, and then washing the polyhydroxyalkanoate with a hydrophilic solvent and/or water."

Harrison et al teaches the same process steps Claims 1, 6, 7, 8, 9, 10, 11, 14, 15, 16 and 20 for the claimed subject matter as recited in the Abstract except for the washing of the PHA with water or hydrophilic solvent:

> Mechanical cell disruption by high pressure homogenisation or high speed bead mills is currently the general method of choice for the large scale disruption of micro-organisms; however, deleterious effects include the high energy requirement, the need for efficient cooling to prevent the excessive heating of the product and the micronisation of cell debris. Certain chemical treatments for microbial cell disruption alter the permeability of bacteria and yeasts, allowing partial release of soluble products. Such treatments are insufficient for the recovery of granular intracellular products. As cell wall strength has been cited as a major factor influencing the requirements for efficient mechanical disruption, the use of chemical pretreatment to decrease cell wall strength prior to mechanical breakage by homogenisation has been considered. The :following treatments were shown to increase the sensitivity of the • Gram-negative bacterium, Alcaligenes eutrophus, to disruption: alkaline pH shock, the addition of an anionic detergent, inc,'ease of the monovalent cation concentration, the addition of EDTA and enzymic lysis by lysozyme. These pretreatments allow equivalent disruption to be achieved at lower operating pressures or fewer passes through the homogeniser. Alkaline pH pretreatment at pH 10.5 allowed a 37.5% increase in soluble protein release on subsequent homogenisation. An increase of some 30% in soluble protein release was found following prior addition of 0.137 M monovalent cations (Na÷ or K÷) at 60 °C. Treatment with an anionic detergent showed a considerable decrease in the nUmber of passes required through the homogeniser. Maximum cell rupture can thus be accomplished at reduced energy-

inputs.
Abbreviations: HPH- high pressure homogenisation; PHB- poly-/3-hydroxybutyrate; SDS- sodium

Harrison et al teaches each of the steps required which includes the physical disruption which is carried out by a high pressures homogenizer for the recovery of PHB polymer as well as the pretreatment with an enzyme and or an anionic detergent [surfactant].

Osamu et al teaches the same method steps for the recovery of PHA which includes the step of adding an alkali and/or a surfactant to a suspension of microbial cells of PHA-containing microorganism, as noted to be Alcaligene eutrophus which contains a transferred PHA synthase gene from Aeromonas caviae which reference abstract does not specify that the suspension an aqueous but the Japanese patent indicates that the additives contain water as noted in para [0029]. Osamu teaches in the disclosure on pages 2-3 various copolymers of 3-HB and 3HV.

Osamu clearly indicates the use of a surfactant within the scope of **claim 11.**

The abstract of the Osamu et al reference does not indicate that there is a physical disruption treatment to obtain the PHA from the cell.

Walker et al teaches in Example 1, the process of recovering PBH by adding an alkali to an aqueous suspension of Alcaligenes eutrophus which flocculants were separated by decanting from the aqueous suspension.

The reference decanting step is considered to be a physical separation.

Claims 2, 7 and 8-9

Walker teaches on page 3 that the cells are contacted with a solvent to solubilize the lipids and cells prior to the PHB-extraction.

Walker also teaches that the addition of alkali is added to increase the pH in the range of 8-12 on page 2, pH 8.5-12 on page 3 and pH 9 in Example 1, which is within the scope of the claimed subject matter.

Walker teaches the use of methanol and acetone for washing as taught in Example 1 for **Claims 12-13**

Masako, Reference 2 or Reference 3, each one teaches the advantages of adding an alkali to an aqueous suspension of PHA containing microorganisms by controlling the temperature and concentration to obtain granular particles of the PHA.

Walker does not indicate any specific alkali.

Masako, Reference 3, teaches in column 3 line 29, LiOH, KOH and NaOH.

Claims 3-5

Osamu et al teaches copolymers which includes the 3 HH, 3HB and 3HV.

Claims 6 and 20

Harrison et al clearly teaches the same process for employing a high pressure homogenizer as indicated above.

Honma et al, U.S. 6,808,907 teaches commonly used processes for separating the cells from the PHA products as recited:

> The method for producing polyhydroxyalkanoate according to claim 13, wherein said step of obtaining the crushed product by crushing cells is performed by at least one selected from the group consisting of ultrasonication method, **homogenizer method, high-pressure crushing method**, bead impact method, milling method, grinding method, and freeze-thawing method.

Claim 10

Reference 4 [WO/22659] teaches the addition of an enzyme that aids in the separation and purification of PHA products by dissolving the cell walls, which aids in the recovery of the PHA, which includes the claimed lipid degrading enzymes or/and cell wall degrading enzymes.

Claims 14-20

Walker et al teaches the microorganisms as well as Osamu for the PHA containing microorganism.

Thus, the above references are considered to render the instant claims prima facie obvious in view of the teachings of the references either Osamu or/and Walker further in view of the additional references as noted by 2, 3, 4 and 5 absent unexpected or unobvious results or process steps.

Thus, claim 1 which recites the following:

> " A method for recovering a polyhydroxyalkanoate from a polyhydroxyalkanoate-containing microbial cell which comprises the following steps (a) and (b); (a) a step comprising adding an alkali to an aqueous suspension of the polyhydroxyalkanoate-containing

> microbial cell while stirring and carrying out a physical disruption treatment to disrupt the cell, solubilizing or emulsifying cell substances other than the polyhydroxyalkanoate in said cell, and then separating the polyhydroxyalkanoate from the aqueous suspension, and (b) a step comprising treating the separated polyhydroxyalkanoate with an enzyme and/or a surfactant to solubilize impurities adhering to the polyhydroxyalkanoate or to solubilize them after decomposing, and then washing the polyhydroxyalkanoate with a hydrophilic solvent and/or water.";

Which claimed subject matter is considered to be prima facie obvious in view of the disclosure of the prior art.

Each of the claimed subject matter is clearly anticipated especially in view of step (a) based on Harrison et al, Walker et al or Honma et al for the alkali treating step which includes the physical disruption of the cell.

The step of washing is clearly taught in several of the other references to purify the PHA as taught by Walker et al.

It is acknowledged that not one of the above references anticipates the claimed subject matter for the broad claim 1, however, there is considered absolutely no patentable subject matter that is not obvious over the references of record that demonstrates unexpected or unobvious process steps which includes the alleged unexpected unclaimed process step in the specification which states:

> "a treatment at such a low temperature as 20 to 40.degree. C. becomes possible, and the molecular weight decrease might be suppressed to 10% or less even in the case of PHBH. Namely, it is

particularly preferred to carry out the physical disruption in a pH level of 9 to 13.5, at 20 to 40.degree. C. When the microbial cells are disrupted under such preferable alkali condition, more reproducible result may be obtained." ;

which low temperature disruption by a high pressure homogenizer is clearly taught by the prior art as noted above for the same reasons of lower temperature to obtain a greater disruption of the PHA.

5. **No claim is allowed.**

6. This action has not been made Final in view of the new art.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Lilling whose telephone number is 571-272-0918 and Fax Number is **571-273-8300**. or SPE Jon Weber whose telephone number is 571-272-0925. Examiner can be reached Monday-Friday from about 7:30 A.M. to about 7:00 P.M. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

H.J.Lilling: HJL
(571) 272-0918
Art Unit **1657**
November 29, 2007

Dr. Herbert J. Lilling
Primary Examiner
Group 1600 Art Unit 1657